

## Remarks

### Preliminary Amendment

Claims 1, 6-9, 11, 12, 14-38, and 57-62 are pending after entry of this Amendment. Claims 2-5, 10, and 13 have been canceled in this Amendment (and claims 39-56 were previously canceled). Claims 1, 6-8, 11-13, and 35-38 are amended herein. Claims 57-62 have been added. Claims 1, 37, and 38 are the only independent claims pending.

No fee for additional claims is believed due, since six claims were canceled and six dependent claims were added.

No new matter is added by the amendments and additions made herein.

This Response and Amendment is timely filed in view of the enclosed petition for an extension of time, which extends the period available for response through 3 January 2005 (1 and 2 January 2005 being Saturday and Sunday, respectively).

### Restriction Requirement

In the Restriction Requirement dated 1 July 2004, the Examiner required restriction among Groups designated I-X. As the Applicants' representative explained by telephone to the Examiner, this restriction vitiates the Applicants' invention, in that it fails to recognize the power of the inventive methods to harness previously unconnected observations to predict an individual's susceptibility to bone disease. During the telephone conversation, the Examiner pointed out that the claims, as originally submitted could be interpreted to include polymorphisms in only a single gene. Claim 1 has been amended both to eliminate that interpretation and to comply, as fully as reasonably possible, with the Examiner's desire to restrict the scope of the search necessary to examine the claims.

As amended, claim 1 recites assessing occurrence of disorder-associated polymorphisms in at least two types of genes - those categorized by the Examiner as Groups VI and IX. Because amended claim 1 requires assessment of both types of polymorphisms, the Applicants believe that the amended claim is in compliance with the Examiner's requirement for election of one of

Groups I-X. The Applicants believe it is not possible to elect a single Group I-X identified by the Examiner in a manner consistent with the nature of the invention, and traverse the Examiner's requirement to the extent it is not satisfied by deletion of non-elected subject matter from amended claim 1.

Beginning on page 5 of the Office Action, the Examiner required additional restriction to individual genes numbered 1-19. The Applicants respectfully traverse this rejection. This requirement vitiates the Applicants' invention, in that it entirely ignores what the Applicants have invented (i.e., that disorder-associated polymorphisms of disparate types contribute to bone disorder susceptibility) and instead seeks to force the Applicants' invention into the previously-conventional "one polymorphism - one disorder" stereotype that the Applicants have broken. The Examiner is strongly urged to withdraw this requirement. To the extent the Examiner is unwilling to withdraw the requirement for one gene from those numbered 1-19, the Applicants believe that it is not possible to elect a single Group 1-19 identified by the Examiner in a manner consistent with the nature of the invention, and provisionally elect "a gene which encodes a vitamin D receptor" (corresponds to Group 5) and "the gene which encodes interleukin-6" (corresponds to group 12).

Beginning on page 6 of the Office Action, the Examiner includes a further requirement for election of one of Groups A-E. The Applicants respectfully believe that the elections made above and the amendments made herein are consistent with election of Group A. This election is nonetheless made with traverse, because the restriction ignores what the Applicants have invented (i.e., that disorder-associated polymorphisms of disparate types contribute to bone disorder susceptibility) and instead seeks to force the Applicants' invention into the previously-conventional "one polymorphism - one disorder" stereotype that the Applicants have broken.

Beginning on page 7 of the Office Action, the Examiner includes a further requirement for election of one of groups a)-m). The Applicants strongly traverse this restriction for the same reason - namely, that it ignores what the Applicants have invented (i.e., that disorder-associated polymorphisms of disparate types contribute to bone disorder susceptibility) and instead seeks to force the Applicants' invention into the previously-conventional "one polymorphism - one disorder" stereotype that the Applicants have broken.

The Examiner is instead urged to recast this restriction as an election-of-species requirement for the purpose of advancing examination of the application. The Applicants believe that it is not possible to elect a single Group a)-m) identified by the Examiner in a manner consistent with the nature of the invention, and provisionally elect the polymorphisms corresponding to Groups b) (vitamin D receptor) and e) (interleukin-6).

The Applicants believe that each of claims 1, 6-9, 11, 12, 14-38, and 57-62, as amended or added herein, corresponds to the elections made in this Response.

**Summary**

The Applicant requests entry of this Preliminary Amendment and early and favorable examination of elected claims 1, 6-9, 11, 12, 14-38, and 57-62.

Respectfully submitted,

3 January 2005

(Date)

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